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09/811,094	03/14/2001	Christen M. Anderson	660088.420D4	1063

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	PAPER NUMBER
1653	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No. 09/811,094	Applicant(s) ANDERSON ET AL.	
	Examiner Holly Schnizer	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-112* is/are pending in the application.

4a) Of the above claim(s) *5,6,27,28 and 42-112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,7-26 and 29-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5 and 27, drawn to recombinant expression constructs encoding an ANT1 polypeptide, classified in class 435, subclass 320.1.

II. Claims 6 and 28, drawn to recombinant expression constructs encoding an ANT2 polypeptide, classified in class 435, subclass 320.1.

III. Claims 7 and 29, drawn to recombinant expression constructs encoding an ANT3 polypeptide, classified in class 435, subclass 320.1.

Claims 1-4, 8-26, and 30-41 link Groups I-III. These linking Claims will be examined with respect to the subject matter of the Invention of Groups I, II, or III, if one of these Groups is elected.

IV. Claim 44, drawn to ANT1 polypeptide, classified in class 530, subclass 300.

V. Claim 45, drawn to ANT2 polypeptide, classified in class 530, subclass 300.

VI. Claim 46, drawn to ANT3 polypeptide, classified in class 530, subclass 300.

Claims 42-43 and 47-57 link Groups IV-VI. These linking claims will be examined with respect to the subject matter of the Invention of Groups IV, V, or VI, if one of these Groups is elected.

VII. Claim 58-74, drawn to a method of determining the presence of an ANT polypeptide in a sample, classified in class 435, subclass 7.1.

VIII. Claims 75-84 and 104 drawn to a method for identifying an agent that binds to an ANT polypeptide and an assay plate for high throughput screening of candidate agents that bind ANT polypeptide, classified in class 435, subclass 7.1.

IX. Claims 85-103 and 107-111, drawn to an ANT ligand, classified in class 530, subclass 300.

X. Claims 105-106 drawn to a method of targeting a polypeptide to the mitochondrial membrane, classified in class 435, subclass 317.1.

XI. Claim 112, drawn to a method of treatment comprising administering a pharmaceutical composition comprising an ANT ligand, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the genes encoding ANT1, ANT2, and ANT3 are distinct and encode proteins having different structures, functions, and which are expressed in different tissues. For example, ANT1 is expressed in heart and skeletal muscle; ANT2 appears to only be expressed in neoplastically transformed cells with high glycolytic

rates, in tumors, and tumoral cells; and ANT3 is ubiquitously expressed (Giraud et al. J. Mol. Biol. (1998) 281: 409-418, see p. 409, col. 2; ref. BH in IDS filed 3-16-01 as Paper No. 6). Moreover, while ANT1 and ANT3 export ATP synthesized in the mitochondria to the cytosol, ANT2 appears to translocate glycolytic ATP synthesized in the cytosol, to the mitochondrial matrix (see Giraud et al. p. 413, Col. 2). Because the ANT protein isoforms are expressed in different tissues and have different structures and functions, the polynucleotides encoding them are independent and distinct, one from the other, and could be used for different purposes and have different effects.

The inventions of Groups IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ANT1, ANT2 and ANT3 polypeptides are distinct are unrelated for the reasons stated in the preceding paragraph. ANT1, ANT2 and ANT3 proteins have different structures, functions, and are expressed in different tissues. Because the ANT protein isoforms are expressed in different tissues and have different structures and functions, they are independent and distinct, one from the other, and could be used for different purposes and have different effects.

The inventions of Groups I-VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the expression constructs and host cells of

Inventions I-III, the polypeptides of Inventions IV-VI, and the ligands of Invention IX have different biological structures and different functions. In addition, subject matter of each Group is not coextensive and thus the search for each would constitute a serious burden upon the examiner. For example, the expression constructs of Group I would require consideration of its use for processes other than the production of the protein, such as nucleic acid hybridization assay and the protein would required searches of literature wherein the protein was isolated from its source rather than recombinantly produced using the polynucleotide. Thus, Groups I-III require considerations which are not required in the search for proteins of Groups IV-VI and Groups IV-VI require considerations which are not required in the search for the polynucleotides of Groups I-III. Likewise, the polypeptides of Groups IV-VI have different functions and are used for different purposes than the ligands of Group IX.

The expression vectors of Groups I-III are unrelated to the methods of Groups VII-VIII and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the expression vectors of Groups I-III are not made by nor used in the protein binding assays of Groups VII-VIII or the method of treatment using an agent that binds ANT of Group XI.

Inventions I-III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the expression vectors of Groups I-III can be used in a method of making the polypeptides or in hybridization assays, which are materially different processes than the method of targeting the ANT polypeptide to the mitochondrial membrane of Invention X.

The ANT polypeptides of Groups IV-VI are unrelated to the methods of Groups VII and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Group IV are not made by nor used in the method of screening using an ANT ligand of Group VII or the method of treatment using an agent that binds ANT of Group XI.

Inventions IV-VI are related to the methods of Groups VIII and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups IV-VI can be used in a method of making an antibody or in activity assays, which are materially different methods than the protein binding assays and method of treatment using an ANT ligand of Groups VIII and XI.

The ANT ligands of Group IX are unrelated to the methods of Groups VIII and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ligands of Group IX are not made by nor used in the method of screening using an ANT polypeptide of Group VIII or the method of targeting an ANT polypeptide to the mitochondrial membrane of Group X.

The ligand of Invention IX is related to the methods of Inventions VII and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ligand of Invention XI could be used in a method of inhibiting the activity of the ANT polypeptides, which is materially different than the method of screening for an ANT polypeptide of Group VII or the method of treatment of Group XI. In addition, the ligand could be used in a method of diagnosis, which is materially different from the methods of screening and treatment of Inventions VII and XI.

The methods of Inventions VII-VIII, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions VII-VIII, X, and

XI are materially different each from the other because each is practiced with materially different process steps, technical considerations, and reagents and each is practiced to accomplish a distinct goal.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, the initial requirement of restriction for examination purposes as indicated is proper.

During a telephone conversation with Stephen Rosenman on June 18, 2003 and August 13, 2003, a provisional election was made without traverse to prosecute the invention of Group III, claims 1-4, 7-26, and 29-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-6, 27-28, and 42-112 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

The disclosure is objected to because of the following informalities: There are no sequence identifiers for the sequences listed in Figures 1A, 1B, and 2. Sequence information in the drawings must still be included in a "Sequence Listing" and the sequence identifier ("SEQ ID NO:X") must be used in the drawings or the Brief Description of the Drawings (see 37 C.F.R. 1.821 and MPEP 2429, 22nd paragraph). Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 20-26, 30-38, and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 37 recite "A host cell according to claim 20" however, Claim 20 is drawn to a recombinant expression construct. Therefore, the product (an expression vector or a host cell) being claimed in Claims 36 and 37 is unclear. Correction is required.

Claims 4, 20, 26, and 40 (and dependent claims 21-25, 30-38, and 41) are unclear because they are drawn to recombinant expression vectors and methods of using them wherein the expression vectors contain a nucleic acid sequence encoding

an "animal" or "human" adenine nucleotide translocator. The metes and bounds of these claims are unclear because the sequences that are part of an expression vector are not necessarily those isolated from animal or human samples. On the contrary, nucleic acid molecules may be synthesized synthetically or nucleic acid sequences from animal or human sequences may be modified after isolation. Therefore, the question arises, is a nucleic acid sequence from a human sample wherein one nucleotide mutation has been made after its isolation considered a "human" sequence? If so, how many mutations may be made in the human sequence without it being considered "non-human"? If not, then, in the continuing discovery of new animal and human ANT sequences, how is one to know which sequences are animal or human that remain to be discovered? Thus, the metes and bounds of what sequences are considered to be "human" or "animal" is unclear. Claims 21-26, 30-38, and 41 are rejected because they depend from Claims 4, 20, 26, and 40 yet do not clarify the metes and bounds of the claims from which they depend. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8-17, 20-26, 30-35, and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krief et al. (U.S. Patent No. 6,316,219; filed 09/1998) in view of Ausubel et al. ((Short Protocols in Molecular Biology, 3rd Ed. (1997) John Wiley & Sons, New York, Chapter 13, pp. 26-35 and Chapter 16, pp. 1-7,16 –23m 25-31, 37-54, 58-62) .

Krief et al. teaches an expression construct comprising a nucleic acid molecule encoding the adenine nucleotide translocator, ANT5 (Col. 6, lines 66-Col. 7 line 1, and Claim 1) isolated from human (see sequence listing). Krief et al. suggests adding control regions that regulate expression (see sentence spanning Col. 6-7). Krief et al. teaches that the expression constructs may be used to create fusion proteins wherein the additional sequence is added to aid in purification (Col. 2, lines 35-44). Since adenine nucleotide translocators function in the mitochondrial membrane to transport ATP to and from the mitochondrial matrix, it is an inherent property of ANT proteins, including that described in Krief et al., that they localize to mitochondrial membranes (see Col. 1, lines 31-33). Krief et al. also disclose host cells including bacterial host cells (prokaryotic cells) and yeast, insect (including Sf9 cells), and mammalian host cells

(eukaryotic cells) (see Col. 6, line 35-Col. 7, line 13 and Claim 3). Krief et al. teaches that the expression construct may be a recombinant viral expression construct (Col. 6, lines 56-58). Krief et al. also describe a method of making a recombinant adenine nucleotide translocator using the described expression systems (Col. 7, lines 1-35 and Claim 5) .

Krief et al. only suggests using expression tools well known in the art and specifically claimed in the claims of the instant application and does not specifically teach using a regulated promoter or nucleic acid sequence encoding a repressor or a second nucleic acid sequence encoding an enzyme cleavable by a protease.

Ausubel et al. teach protein expression tools and example protocols of how to use them that were widely available and known to those of ordinary skill in the art at the time of the invention. Ausubel et al. teaches that the particular technique and particular host cell used in expressing a protein depends on a wide variety of factors including time and expense and the desired use of the protein (for crystallography, function analysis, localization analysis, for example) and that each host cell has its advantages and disadvantages (p. 16-2). Ausubel et al. provides evidence that at the time of the invention inducible promoters and repressors were known to those of skill in the art (for example, see p. 16-28 describing the pGEX1 vector with the lac repressor (product of the lacI gene)and the ptac promoter inducible by IPTG for expression in E. coli or the yeast vectors containing inducible promoters in Table 13.5.1). Ausubel et al. also provides evidence that making fusions between the DNA encoding the protein of interest with an enzyme (as lacZ) wherein the two sequences are cleavable by a

protease provides advantages such as better expression, ease of localization, and ease of purification (see pages 16-16 through 16-31).

Therefore, as described above expression tools such as prokaryotic and eukaryotic (including yeast, insect, and mammalian) host cells, regulated promoters, repressors, and fusion systems were very well known and available to those of ordinary skill in the art at the time of the invention. In other words, as suggested by both Krief et al. and Ausubel et al., given knowledge of an amino acid or nucleotide sequence encoding a desired protein, one of ordinary skill in the art at the time of the invention could have chosen the expression construct, host cell, and method of making a protein most suitable to their needs to express the desired protein. It would have been obvious to one having ordinary skill in the art at the time of the invention to express the DNA sequence encoding ANT5 described by Krief et al. using the methods disclosed in Ausubel et al. Adenine nucleotide translocators are membrane proteins. Overexpression of membrane proteins leads to a high amount of protein in the membrane of the protein and can be toxic to the cell. Therefore, one of ordinary skill in the art would have motivation to use an expression construct having an inducible promoter and a repressor as suggested by Kreif et al. (p. sentence spanning Col. 6-Col. 7) in order to minimize expression until desired (see p. 13-27 of Ausubel et al. under "Promoters") and thereby maximize the quantity of the protein produced. One of ordinary skill in the art would have had motivation to use an expression construct wherein the DNA encoding the ANT protein was fused to an enzyme such as lacZ and wherein the two proteins could be cleaved by a protease because such a construct

would facilitate expression and recovery (including the purification of the protein and the visualization of the protein fractions during purification or in studying localization of the protein in the cell).

Claims 7 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krief et al. and Ausubel et al. as applied to claim1-4, 8-17, 20-26, 30-35, and 38-41 above, and further in view of Cozens et al. (J. Mol. Biol. (1989) 206: 261-280; ref. BF of IDS of Paper No. 5).

The teachings of Krief et al. and Ausubel et al. have been described above.

Neither Krief et al. nor Ausubel et al. disclose the DNA or amino acid sequence of ANT3.

Cozens et al. teach the sequence of the DNA encoding the human mitochondrial ADP/ATP translocase protein, ANT3. The examiner notes that the nomenclature used in Cozens for the ANT3 protein is T2.

Thus, at the time of the invention the sequence of ANT3 was well known to those of ordinary skill in the art as evidenced by Cozens et al. As suggested in Krief et al. and discussed in Ausubel et al. a number of inducible promoters for expression of recombinant proteins in various types of host cells were also well known to those of skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods of Krief et al. and Ausubel et al. to make an expression vector encoding ANT3 using the sequence disclosed in Cozens et al. One having ordinary skill in the art would have been motivated to do this so that the ANT3

protein could be expressed in high amounts for studying the localization and functions thereof.

Claims 18, 19, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krief et al. and Ausubel et al. as applied to claims 1-4, 8-17, 20-26, 30-35, and 38-41 above, and further in view of Le Saux et al. (Biochemistry (1996) 35: 16116-16124) and Wallace et al. (WO 98/19714,; Ref. AE of IDS of Paper No. 5).

The teachings of Krief et al. and Ausubel et al. have been described above.

Krief et al. and Ausubel et al. do not disclose a host cell that lacks at least one isoform of an endogenous adenine nucleotide translocator.

Le Saux et al. describes a yeast host cell that lacks all isoforms of the adenine nucleotide translocator except for ANC2 (p. 16116, Col. 2, lines 7-9). Le Saux et al. teach that studies of the conformational changes of the adenine nucleotide translocator were hampered because the fluorescence signals used to study these changes only provided a global assessment of the conformational changes of the bulk of the carrier isoforms (p. 16122, Col. 1, last paragraph). Therefore, a host cell lacking all but one isoform, like that disclosed in Le Saux et al., was desired for the studying of the individual isoforms.

Wallace et al. provides evidence that animal host cells can be made wherein an individual adenine nucleotide translocator isoform gene is impaired such the host cell lacks that isoform (see examples).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify a host cell containing an expression construct comprising an inducible promoter operably linked to a sequence encoding an adenine nucleotide translocator as taught in Krief et al. and Ausubel et al. such that the host cell lacks at least one endogenous ANT isoform or such that the gene encoding at least one ANT isoform is impaired as taught by Le Saux et al. and Wallace et al. One of ordinary skill in the art at the time of the invention would have been motivated to do so because as suggested in Le Saux et al. such a host cell allows for the study of individual ANT isoforms or as suggested by Wallace et al. such a host cell allows for the study of the effect a deficiency of particular ANT isoforms on cellular function (see Wallace et al. p. 2, lines 27-30).

Conclusions

The ANT3 sequence was well known at the time of the invention as evidenced by Cozens et al. Combining this known sequence with well known expression constructs and host cells does not make the ANT sequence patentable especially in light of the prior art disclosure of expression constructs and host cells containing related ANT sequences and their successful use in expression (in Le Saux et al. and Adrian et al. (ref. AH in IDS of Paper No. 5).

Therefore, no claims are allowable for the reasons cited in the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-

3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
September 2, 2003

Christopher S. F. Low

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